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10/806,483	03/22/2004	Hans-Juergen Kuhr	9134-0252	2791

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EXAMINER	
LANG, AMY T	

ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/806,483	KUHR ET AL.	
	Examiner	Art Unit	
	AMY T. LANG	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the blocking mechanism breaking the needle body must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections – 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Claims 7, 9, 13, 16, and 21-39** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 13, 21, 35, and 38 recite wherein the needle housing "changes shape" or is "enlarge[d]" to prevent re-use of the needle. However, it appears as though the housing comprises a fixed shape and the holding elements changes position to activate the blocking mechanism and prevent reuse of the needle. For instance, Figures 1b and 1d show the proximal end of the needle body (6) moving distally so that the needle tip pierces a patient. After the lancing operation has been carried out, the proximal end of the needle body is prevented from moving to its initial proximal position due to the interaction of lugs (12) with recess (13) of the housing (see paragraph [0045] of the amended specification). Therefore, the lancet is no longer able to be activated. As shown in Figure 1d, in this position, the holding element (lug 12) has moved in position so that it now sticks out from the needle housing (2a), but the outer housing has not moved in position. Similarly, the housing in Figure 7 also does not change shape since the elastic arms (30) move position to prevent reuse of the lancet. Therefore, the

instant specification and Figures do not support the needle housing as actually changing shape or enlarging in shape. Claims 22-34, 36-37, and 39 are dependent on claims 21, 35, and 38 and therefore are also not supported by the instant disclosure.

Claims 7 and 9 recite wherein the blocking mechanism is actuated either when the lancet system is removed from the lancing housing or during a lancing operation. However, the species currently claimed, Figure 7, only recites when the blocking mechanism is actuated when the lancet system is inserted into the lancing aid (see paragraph [0060]). Therefore, claims 7 and 9 also are not supported by the instant specification.

Claim 16 recites wherein the blocking mechanism "destroys" the holding element of the lancet system. However, the amended specification does not support this limitation.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claims 1-20, 34, 40, and 41** rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 12, and 34 recite wherein "the protective portion ... and the needle can be moved relative to one another" so that the needle moves relative to the protective portion and the protective portion moves relative to the needle. It is the Examiner's understanding that the "protective portion" refers to an elastomeric protection (4) so that

it is not clear as to how the protective portion can move relative to the needle. It is clear from the amended specification and Figures that that needle moves relative to the protective portion to pierce a patient. However, the protective portion appears to stay in place so that it does not move relative to the needle. Claims 2-11, 13-20, 40, and 41 are dependent on claims 1 and 12 and therefore are rendered indefinite.

Although the instant amended specification also recites a "protective portion of the needle housing" (see for example paragraph [0045]), this component cannot be the claimed protective portion. The instant claims teach the protective portion as separate from the needle housing and therefore cannot be part of the needle housing (the claims two separate components not one as part of the other). Therefore, the claimed protective portion can only be the elastomeric protection (4). If this assessment is incorrect, clarification is required.

Claim 10 recites wherein the protective portion of the needle housing is transferred to a first position. However, even if the protective portion is referring to the needle housing (2a), the needle housing does not appear to move in position. Instead, as shown in Figures 7a-7c, only the blocking mechanism (31) and the recesses (95) move in position. Therefore, the claimed protective portion is indefinite.

In **claim 21** there exists an inconsistency thus making the scope of the claim unclear. First Applicant recites "a needle housing configured for insertion into a lancing aid" with the lancing aid only being functionally recited. This indicates that the claim is directed to the subcombination, "a needle housing." However, Applicant later recites "the needle housing is removed from the lancing aid," thus indicating that the

combination (needle housing and lancing aid) is being claimed. As such, it is unclear whether Applicant intends to claim the subcombination or the combination. Applicant is hereby required to indicate to which, combination or subcombination, the claim is intended to be directed and amend the claim such that the language is consistent with this intent. Claims 22-33 are dependent on claim 21 and are therefore also rendered indefinite.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. **Claims 1, 3, 5-9, 11, 12, 17, 20, 40, and 41** are rejected under 35 U.S.C. 103(a) as being unpatentable over Schraga (US 2002/0077650 A1) in view of LeVaughn et al. (US 2005/0015020 A1).

With regard to **claim 1**, Schraga et al. (hereinafter Schraga) discloses a lancing aid for producing an opening in the skin (see entire document). The lancing aid comprises a housing (20) having a holding element (24) (Figure 1). A lancet system (30) is disposed within the housing and comprises a holding element (52) (Figure 2). As shown in Figure 3, the housing holding element and the lancet system holding element interact when the lancet system is positioned in the housing.

Schraga further discloses the lancing system as comprising a needle having a tip (24) and that is connected to a needle housing (32) (Figure 2). The needle is movably connected to the needle housing since the two components are able to move from a cocked orientation to a firing orientation (Figures 3, 4, and 6). During the firing process, the needle tip (34) emerges from an opening (22) in the housing to pierce a patient ([0021]).

After the firing process, the needle is prevented from firing again due to activation of a blocking mechanism ([0029]). Abutment (64) on the housing prevents the housing holding element (24) and the lancet holding element (52) from interacting (Figure 4). Without such an interaction between these two components, the lancet is unable to be re-fired. Therefore, the abutment on the housing clearly produces the claimed blocking element.

However, Schraga does not disclose a protective portion. LeVaughn et al. (hereinafter LeVaughn) teaches that it is advantageous for a lancet system to comprise a protective portion. A sterility barrier over the needle tip helps to enclose the needle and therefore ensures the needles are safe and sterile ([0019]; [0106]). Since the

needle tips are able to penetrate through the barrier, it is able to be used with an additional needle cap ([0019]). Therefore, it would have been obvious at the time of the invention for the lancing aid of Schraga to further comprise a barrier. This would advantageously provide increased safety and sterility to the needle tip.

The barrier, as disclosed by LeVaughn, clearly overlaps the instantly claimed protective portion since it surrounds the needle tip in a first position (see Figure 4 of LeVaughn). When the lancet is activated, the needle tip penetrates through the barrier so that it extends from the barrier. Therefore, Schraga in view of LeVaughn overlap the instant claim.

With regard to **claim 3**, the housing and lancet system of Schraga each have independently acting holding elements (24 and 52 respectively).

With regard to **claims 5 and 6**, the blocking mechanism of Schraga prevents the needle from being propelled forward since the holding elements are spatially separated (Figure 4).

With regard to **claims 7 and 9**, the blocking mechanism is actuated when the lancet system, specifically the needle tip, is removed from the housing during a lancing operation. The needle tip propelling forward to pierce a patient ultimately causes the blocking mechanism to prevent re-fire.

With regard to **claim 8**, conversely the blocking mechanism is also actuated when the lancet system, specifically the needle tip, is inserted back into the housing. When the needle tip re-enters the housing, the abutment (64) prevents the holding elements from interacting (Figure 4).

With regard to **claim 11**, the first position of the barrier of LeVaughn, the protective portion, is its resting position since it does not move in position.

With regard to **claims 12 and 20**, it is also the Examiner's position that shoulder element (62) overlaps the instantly claimed blocking mechanism ([0030]). As shown in Figure 4, this blocking mechanism is movable relative to the housing (20) and prevents the holding elements from interacting. This blocking mechanism "changes" the shape of the housing since it no longer allows holding element (52) to protrude from aperture (24), as shown in Figure 3. Therefore, the blocking mechanism changes the outer surface area of the lancing aid by reducing the outer surface area.

With regard to **claim 17**, as shown in Figure 2 of Schraga, the needle housing comprises the needle housing holding element.

With regard to **claim 40**, the blocking mechanism, once activated is covered by the housing (20) (Figure 4).

With regard to **claim 41**, the holding element of the needle housing (52) is a flexible arm member (Figure 2).

9. **Claims 21-23, 25, and 29-32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Schraga (US 5,797,942) in view of Looper (US 2003/0114839 A1).

With regard to **claim 21**, Schraga discloses a lancet system comprising a needle housing (10) that is configured for insertion into a lancing aid (110) (Figures 2 and 5A). A needle with a needle tip (61) is movably mounted to the needle housing (Figure 2; column 5, lines 15-20). The needle is movable from a first resting position in which the

needle housing partially surrounds the tip to a lancing position where the tip is exposed through opening (19) (column 5, lines 37-44). The needle then moves to a third position, as shown in Figure 5B, where the needle housing partially surrounds the tip again. This third position is maintained when the needle housing is removed from the lancing aid (column 9, lines 5-16). The needle is movable to and from the lancing position multiple times until a user activates the engagement means (30) that prevents re-use (column 9, lines 15-25).

After a user is done with a specific needle, needle housing (10) is then removed from the lancing aid (column 9, lines 15-16). This needle is now deemed contaminated and should be properly disposed of (column 9, lines 26-30). However, Schraga does not specifically teach wherein the needle housing (10) is unable to be re-inserted into the lancing aid.

Looper discloses a surgical device wherein a distal end effector is prevented from re-use (see entire document). The end effector includes a biopsy collector, which encompasses lancet devices, and is connected to the shaft of the surgical device through a frangible portion ([0014]; [0017]; [0040]). Once the distal end effector has been utilized and is contaminated, the frangible connection is distorted so that the connection between the surgical device and the end effector is prevented (Figures 2 and 3). This assures that the end effector is used only once for safety ([0043]; [0047]).

Schraga discloses a lancing device with a detachable end effector, the needle housing, that once used is contaminated and must be disposed of for safety issues. It is well known in the art to one of ordinary skill that contamination from a lancet can poses

a health hazard if not properly handled. Looper teaches an advantageous blocking method wherein the end effector is prevented from being used more than once so that a contaminated end effector is not re-used. Since Schraga is open to various modifications and Looper teaches an advantageous way to prevent a lancet needle from being used more than once, it would have been obvious to one of ordinary skill at the time of the invention for the needle housing of Schraga to comprise the blocking mechanism of Looper so that the needle housing of Schraga has a frangible connection with the lancing aid.

With regard to **claim 22**, although Looper teaches the blocking mechanism actuated when the end effector is removed from the surgical device, Looper does not specifically disclose the actuation when the end effector is connected to the device or during the lancing operation. However, it would have been obvious to one of ordinary skill at the time of the invention for the blocking mechanism to be actuated when connected to the device or during the lancing operation. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify when the frangible connection is broken because Applicant has not disclosed that actuating the actuation before, during, or after the lancing operation provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the actuation when the lancet is removed because the connection is still broken to prevent re-use.

With regard to claim 23, the needle housing (10) comprises hole (19) through which the needle tip (61) emerges in the lancing position (Figure 5A). Additionally, this hole is configured for alignment with a separate lancing aid (specifically, a separate lancing aid than that disclosed by Schraga).

With regard to **claims 25 and 29**, Schraga in view of Looper disclose a lancing aid that is prevented against re-use. Looper teaches that it would have been obvious for the lancing aid of Schraga to comprise a frangible connection between the lancet system and lancing aid and produce a blocking mechanism. This blocking mechanism prevents a holding element of the lancing aid from interacting with a holding element of the needle housing. Therefore the needle housing would no longer able to connect with the lancing aid. The points at which the two components connect are independently the claimed holding elements.

With regard to **claim 30**, Schraga discloses that the first position is the same as the resting position (column 5, lines 44-46).

With regard to **claims 31 and 32**, since the lancet system of Schraga is able to move between a resting position and a lancing position until engagement means (30) is activated by the user (Figures 5A and 5B), the needle is therefore configured to move between these two positions multiple times after the needle body is inserted into the lancing aid. Furthermore, it is the examiner's position that the needle is also configured to move between the second resting position and the lancing position after the blocking mechanism is actuated. The blocking mechanism of Schraga in view of Looper only prevents a used lancet from being re-inserted into the lancing aid. It does not prevent a

lancing needle from firing into a patient. Although Schraga in view of Looper do not specifically teach re-using a needle before the lancet system is removed from the lancing aid, it is the examiner's position that Schraga in view of Looper is capable and configured to.

Allowable Subject Matter

10. Claims 2, 4, 10, 13-16, 18, 19, 24, 26-28, and 33-39 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Response to Arguments

11. Applicant's arguments filed 09/10/2008 with respect to claims 1-41 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

04/07/2009
/Amy T Lang/
Examiner, Art Unit 3731

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